

December 12, 2003

Mr. Alex Marion
Nuclear Energy Institute
1776 I Street, NW., Suite 400
Washington, DC 20006-3708

Mr. David Lochbaum
Union of Concerned Scientists
1707 H Street, NW
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Washington, DC 20006-3919

SUBJECT: THE INTERIM STAFF GUIDANCE PROCESS

Dear Messrs. Marion and Lochbaum:

The staff issued a draft of the interim staff guidance (ISG) process for comment on July 30, 2002. By letter dated October 29, 2002, Nuclear Energy Institute (NEI) provided comments on the draft ISG process. The staff has revised the ISG process and enclosure 1, the Process for Interim Staff Guidance Development and Implementation, provides the final guidance. NEI's comments and the staff's responses are discussed in enclosure 2.

The ISG process captures lessons learned from license renewal reviews and communicates them to the stakeholders. The process includes interaction with stakeholders during the development of the ISG, including publishing of a *Federal Register* notice requesting comments. If the ISG is approved, then an applicant for a renewed license needs to address the issue.

Once an ISG is approved, it will be incorporated into the next revision of the license renewal guidance (LRG) documents. The three guidance documents are NUREG-1801, "Generic Aging Lessons Learned (GALL) Report," NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR), and Regulatory Guide 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses." The Nuclear Regulatory Commission (NRC) has endorsed Nuclear Energy Institute, NEI 95-10, Revision 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule," and NEI has indicated that it will update this guidance in accordance with the approved ISGs.

For licensees holding a renewed license, the license renewal regulations in 10 CFR 54.37(b) requires that after the renewed license is issued, the final safety analysis report update (FSAR) required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in 10 CFR 54.4(b) will be effectively maintained during the period of extended operation. Therefore, for ISGs involving newly identified systems, structures and components (SSCs) that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the LRG documents are updated, the staff will wait until the ISGs have been incorporated into the LRG documents before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. The review process for revising NUREGs, like NUREG 1800 and 1801, involves public comment and review by the Committee to Review Generic Requirements. After the LRG documents have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

Changes were made to the ISG process as a result of your comments and further staff review. Should you have questions, please contact Mr. Jack Cushing of my staff at (301) 415-1424.

Sincerely,

/RA/

David B. Matthews, Director
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

Project No. 690

Enclosures: As stated

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*See previous concurrence

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DATE	10/20/03	10/31/03	12/12/03

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Project No. 690

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**Process for Interim Staff Guidance
Development and Implementation**

Process for Interim Staff Guidance Development

1.0 POLICY

Part 54 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 54), hereafter referred to as "the rule," governs the issuance of renewed operating licenses for nuclear power plants. To facilitate the implementation of the rule and the review and inspection of programs and activities associated with a license renewal application (LRA), the staff has developed license renewal guidance (LRG) documents.

The LRG documents are:

- NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR)
- NUREG-1801, "Generic Aging Lessons Learned (GALL) Report"
- Regulatory Guide (RG) 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses"

In addition, the Nuclear Energy Institute (NEI) developed the following document that is endorsed in RG 1.188:

- NEI 95-10, Revision (Rev.) 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule"

The SRP-LR provides guidance to Nuclear Regulatory Commission (NRC) staff reviewers in the Office of Nuclear Reactor Regulation (NRR). These reviewers perform safety reviews of applications to renew nuclear power plant licenses in accordance with the license renewal rule. The principal purposes of the SRP-LR are to ensure the quality and uniformity of staff reviews and to present a well-defined base from which to evaluate applicant programs and activities for the period of extended operation. The SRP-LR is also intended to make information about regulatory matters widely available, to enhance communication with interested members of the public and the nuclear power industry, and to improve the public's understanding of the staff review process. Each of the individual SRP-LR sections addresses (1) who performs the review, (2) the matters that are reviewed, (3) the basis for review, (4) the way the review is accomplished, and (5) the conclusions that are sought.

The SRP-LR references the GALL report (which evaluates existing programs), generically, to document (1) the conditions under which existing programs are considered adequate to manage identified aging effects without change and (2) the conditions under which existing programs should be augmented for this purpose. The GALL report should be treated as an approved topical report (as explained in NUREG-1739).

The purpose of RG 1.188 is to provide guidance to an applicant on the information to be submitted in an application for renewal of a nuclear power plant operating license in a uniform format that is acceptable to the NRC staff for structuring and presenting this information. It also endorses NEI 95-10, Rev. 3, as an acceptable method for implementing the requirements of the license renewal rule.

NEI 95-10 was developed by the NEI License Renewal Implementation Guideline Task Force and the NEI License Renewal Working Group for the implementation of the license renewal rule.

The license renewal program is a living program. The staff, industry, and other interested stakeholders gain experience and develop lessons learned with each renewed license. The lessons learned address the NRC's performance goals of maintaining safety, improving effectiveness and efficiency, reducing regulatory burden, and increasing public confidence. The lessons learned are captured in interim staff guidance (ISG) for use by the staff and interested stakeholders until the LRG documents are revised.

2.0 OBJECTIVES

This instruction ensures that proposed changes to the LRG documents are properly evaluated, documented, and implemented. Further, this instruction establishes the responsibilities and authorities for the NRR staff in identifying changes to the LRG using the ISG process.

This instruction provides NRR staff with the basic framework for processing ISGs. The goals of this instruction include the following:

- To ensure the continued health and safety of the public
- To improve public confidence in the license renewal process
- To implement a documented and controlled license renewal review process, so as to reduce unnecessary regulatory burden
- To maintain a consistent, effective, and efficient review process.

3.0 BACKGROUND

The LRG documents have been developed to enhance the license renewal process. It is expected that, as lessons are learned during LRA reviews, these guidance documents may need to be modified to capture new insights or address emergent issues. This process serves to expeditiously address specific areas in the LRG documents that need to be revised and to serve as a bridge until the entire document can be revised.

Public involvement is an important part of this process. The process, as described in Section 4.0 of this document, gives the public opportunities to obtain information and to comment on the proposed ISG. ISG's will be discussed in public meetings. The staff will respond in writing to any written comments. The public will also be able to comment when the LRG documents are revised to include the ISGs. The NRC will make ISGs available to the public by publishing them on the NRC web site, in Agency Documents Access and Management Systems (ADAMS), and by holding public meetings, as appropriate.

4.0 ISG PROCESS

4.1 Overview

The staff, industry, or interested members of the public may comment or propose changes to information provided in an LRG document. Some comments may warrant the staff's developing and issuing an ISG prior to the next update of the LRG documents. Each ISG will be incorporated into the periodic updates of the LRG documents. For comments that do not result in an ISG, the ISG coordinator will evaluate the comments to determine if they should be addressed in the next revision of the LRG documents.

Failure to follow the ISG process might adversely affect the stability and predictability of the license renewal program. During the course of an LRA review, the staff may discover an issue that would expand the scope of the issues being addressed under the LRG documents. The staff should not ask an applicant to address the new issue through a request for additional information (RAI) until an approved ISG has been issued. The ISGs have schedule implications for current and future applicants for license renewal and licensees holding a renewed license may be required to address the ISG in their next final safety analysis report (FSAR) update. Therefore, the structured approach described in this instruction should be followed.

The process is administered and controlled by the License Renewal Section B in the License Renewal and Environmental Impacts Program (RLEP), Division of Regulatory Improvement Programs (DRIP), NRR. Expected primary contributors to the process are NRR, and the Office of Nuclear Regulatory Research (RES).

The ISG coordinator and ISG lead project manager (PM) play vital roles in the ISG process. They are responsible for screening, documenting, planning, tracking, coordinating, and implementing resolutions of license renewal proposed ISGs. Technical reviewers will be assigned to support the development of each ISG.

The staff evaluating ISGs should be familiar with the following documents:

- 10 CFR Part 54 and the associated statements of consideration (60 FR 22461 as amended by 61 FR 65175 and 64 FR 72002)
- RG 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses"
- NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants" (SRP-LR)
- NUREG-1801, "Generic Aging Lessons Learned (GALL) Report"
- NEI 95-10, Revision 3, "Industry Guideline for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule."

In using these guidance documents, the staff, industry, or member of the public may discover guidance that is unclear, incorrect, or incomplete, or may find that new guidance is warranted. Comments can be provided to the ISG coordinator orally, by e-mail, or by letter. The ISG coordinator will document the comment. Oral comments made during public meetings will be reflected in the meeting summary. Disposition of such oral comments will either be reflected in the meeting summary, a proposed ISG, or a written response to the commenter.

Once documented, the issue will be controlled by this process to ensure timely resolution. If the staff determines that development of an ISG is warranted, then it will issue a *Federal Register* notice (FRN) requesting comments (60 day comment period) on the proposed ISG. At any step during the process, a proposed ISG can be modified or determined to be unnecessary. If a proposed ISG is determined to be unnecessary, the staff will document the closure of the issue in a letter to the interested stakeholders, and a FRN. The approved ISGs will be published on the NRC license renewal web site. The ISG will be incorporated into the next revision of the LRG documents. Appendix B to this instruction provides a flow chart of the process.

4.2 Processing License Renewal Proposed ISGs

The basic activities are as follows:

- Section 4.2.1 - Screen Comments
- Section 4.2.2 - Develop an Evaluation Plan
- Section 4.2.3 - Evaluation and Transmittal of Proposed ISG
- Section 4.2.4 - Resolution of Comments on the ISG
- Section 4.2.5 - Implementation of the Approved ISG

These basic activities are described in the sections below.

4.2.1 Screen Comments

The process starts when the NRC staff, industry, or members of the public submit a comment to the ISG coordinator on the LRG documents. Stakeholder requests are expected to be brought to the NRC's attention via letter, telephone call, or e-mail. Once RLEP is notified, the issue will be referred to the ISG coordinator for review. The ISG coordinator screens, tracks, and documents the comments.

The ISG coordinator will screen the comments to determine if development of an ISG is warranted. Development of an ISG is not necessary if adequate staff guidance is already available. No ISG is developed if the comments are determined to be purely editorial comments. These editorial comments improve the readability and consistency of the documents and would not cause a current or future applicant to revise their LRA. The ISG coordinator will ensure the comments are evaluated for inclusion in the next revision of the LRG documents. The originator will be informed of the resolution.

An ISG will be developed if the comment would result in a staff position or guidance that needs to be communicated to external stakeholders, such as current or future applicants, so that they can address it in their LRAs. The staff will commence developing the ISG in accordance with the guidance contained in this document. The ISG coordinator's actions for this section are discussed below.

ISG Coordinator Actions

The ISG coordinator will:

- Request that the originator forward the basis for the proposed ISG in writing. The basis should include the need and the underlying regulatory requirement that the proposed ISG would address. The originator should, but is not required to, provide a markup of the LRG to communicate their proposed resolution. External stakeholders should be encouraged to submit their comments in a letter or e-mail to the RLEP program director (PD-RLEP). If needed, the ISG coordinator will arrange a conference call or public meeting to discuss the ISG.
- Screen the proposed ISG to determine whether interim staff guidance is necessary. The ISG coordinator may involve technical branches from other NRR divisions or NRC offices during the evaluation of the issue.
- Ensure that a written response has been provided to the originator within 30 days following receipt of the proposed ISG. The response should indicate how the issue was previously resolved or the current status of the review.
- Issue a FRN requesting comment on the proposed ISG (60 day comment period). The notice will be a short summary of the proposed ISG and will include the ADAMS accession number for the proposed ISG.

4.2.2 Develop an Evaluation Plan

Planning the processing of a proposed ISG is a critical step in ensuring that the review is completed in a timely and effective manner. The plan is intended to define the scope of the review, the resources needed for the review, and the schedule for resolution.

Developing the evaluation plan involves the following activities:

- The ISG coordinator should determine the schedule for completing initial review and discuss this determination with the Chief of RLEP License Renewal Section B for confirmation.
- The ISG coordinator should discuss the schedule for completing the initial review with the originator.
- The Chief of RLEP License Renewal Section B will assign an ISG lead PM for each proposed ISG to develop a proposed resolution.

- Upon acceptance of a proposed ISG, the ISG lead PM will obtain a technical assignment control (TAC) number, if necessary. This provides a means of tracking the resources expended and the work activities on each review. Separate TAC numbers are appropriate if significant resources (i.e., more than eight hours) are expected to be expended for a particular issue.
- The ISG lead PM will assess the proposed ISG to define the scope, resources, and schedule for resolution. This should include a discussion with the technical branch to determine the type of ISG (i.e., clarification or compliance).
- The ISG lead PM will be responsible for coordinating the activities documented in the evaluation plan, monitoring the progress of these activities, and reporting the status of the review to the ISG coordinator for tracking by RLEP.
- The ISG lead PM will be responsible for obtaining clarification of the input from the originator or stakeholder. It is expected that the input will be clearly written with a proposed resolution for the identified concern. The input should, but is not required to include a markup of the guidance document that warrants modification.
- The ISG coordinator will track and monitor the proposed ISG's progress toward resolution.

4.2.3 Evaluation and Transmittal of Proposed ISGs

4.2.3.1 Evaluation of Proposed ISGs

There are two types of ISGs, (1) clarification ISGs and (2) compliance ISGs. Clarification ISGs provide additional guidance to applicants that the staff or stakeholders feel is necessary to reduce unnecessary RAI. Clarification ISGs do not create new staff positions that have not been addressed by previous applicants. Clarification ISGs can inform applicants that more information is needed on an issue already addressed in the LRG documents. Clarification ISGs do not apply to licensees holding a renewed license. Compliance ISGs involve compliance with the regulations and therefore do apply to licensees holding a renewed license.

The memorandum transmitting the proposed ISG from the branch chief of the technical branch to the PD-RLEP will specify if the ISG is a clarification or compliance ISG. The transmittal memorandum for clarification ISGs may be signed by the branch chief. The transmittal memorandum for compliance ISGs will contain a documented evaluation. The technical branch division director's concurrence in the memorandum is necessary.

The ISG lead PM will coordinate the review and the proposed resolution. Office of General Council (OGC) review of a proposed ISG is necessary. The ISG lead PM assigned to resolve the proposed ISG is also responsible for coordinating the staff's evaluation with all involved branches and offices.

Proposed ISGs involving multiple branches and/or offices may result in scheduling and resource conflicts or staff disagreements on the proposed resolution of the issue. The ISG lead

PM is responsible for notifying management and the ISG coordinator of these conflicts and for coordinating discussions that lead to a consensus staff position.

Some proposed ISGs may involve policy issues that warrant Commission involvement. These issues can be identified at any time in the planning and evaluation process and need to be discussed with the PD-RLEP as soon as the potential for a Commission-level issue is identified. RLEP will document the proposed ISG, the proposed options, and a staff recommendation before presenting the proposed ISG to management for submittal to the Commission. Upon receipt of the Commission's directions on the ISG, the staff will take the appropriate action implementing the Commission's decision.

4.2.3.2 Transmittal of Proposed ISGs

Once a proposed ISG is developed, it will be documented and transmitted to the originator and stakeholders for feedback. The ISG coordinator will issue an FRN requesting comment on the proposed ISG (60 day comment period). The notice will be a short summary of the proposed ISG and will include the ADAMS accession number for the proposed ISG. The following provides guidance for the format and content that should be used for all ISGs:

Issue Heading:

A short summary or description of the issue (one or two sentences). Keyword searches in ADAMS could be generated from the summary, so it is beneficial to be specific.

Staff Position:

This section describes the proposed ISG and the proposed resolution.

Rationale:

This section should provide a description of the issue in sufficient detail, such that an informed reader can understand the issue, its basis, significance, applicability (e.g., generic, BWRs only), and ramifications. The staff will document its analysis of the proposed ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.

References:

List references mentioned in the ISG text. These could include the ASME and ANSI Codes, NUREGs, other ISGs, Part 54 subsections, and Regulatory Guides.

Attachments:

This section contains the staff's markup of existing or new guidance that implements or incorporates the staff's proposed resolution of the issue (including the SRP-LR, GALL, RG 1.188, and/or NEI 95-10) and should normally be provided for all changes.

4.2.4 Resolution of Comments on the ISG

It is the ISG lead PM's responsibility to prepare a letter to solicit comments on the proposed resolution of the issue. The letter should be addressed to NEI and to the Union of Concerned Scientists (UCS), as the coordinator for public interest groups and published on the NRC license renewal web site. Current license renewal applicants, other stakeholders on the license renewal service list, and the originator will be sent a copy of the letter. Typically, the letter should be reviewed by the technical branch supporting the ISG, OGC, and PD-RLEP. Review and concurrence should ensure the quality and consistency of the proposed resolution of the issue. Typically, the letter will request comments on the proposed ISG within a 60-day period. For complex issues, a longer comment period may be considered. At the same time a FRN requesting comments on the proposed ISG will be issued with the same comment period as the letter.

Comments should be provided in writing to the PD-RLEP within the comment period. A public meeting or conference call (minutes to be published in ADAMS) may be conducted to clarify the concern. Appropriate comments will be addressed in approved ISG published on the NRC web site.

Once the staff has made its determination, the proposed ISG will be considered resolved. The final resolution could be approval or a determination that the proposed ISG is unnecessary. The division director of DRIP will normally sign all proposed resolution letters, unless otherwise specified by NRR Office Instruction ADM-200, "Delegation of Signature Authority." The staff will post the approved ISG on the NRC License Renewal web page for staff and industry use and will issue an FRN informing stakeholders that an ISG has been approved and is available on the NRC web site. The FRN will reference the ADAMS accession number for the approved ISG. At this point, the approved ISG will have a number designation and an implementation date. The ISG can then be referenced in an applicant's LRA or as part of the LRA regulatory review process. The ISG will be incorporated into the next revision of the LRG documents.

4.2.5 Implementation of the Approved ISG

Implementation of compliance ISGs affects both future and current applicants. Future applicants will address the ISG in their LRA. Current applicants will address the approved ISG by responding to an RAI, by addressing an open item in the draft SER, or by supplementing their application.

For licensees holding a renewed license, the license renewal regulation in 10 CFR 54.37(b) require:

After the renewed license is issued, the FSAR update required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with §54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in §54.4(b) will be effectively maintained during the period of extended operation.

Therefore, only for ISGs involving newly identified systems, structures and components (SSCs) that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed. ISGs that do not involve newly identified SSCs would for licensees holding a renewed license, be subject to the requirements of the 10 CFR 50.109, the backfit rule. For example, for licensees holding a renewed license, a change to an existing aging management program would require a backfit evaluation in accordance with 10 CFR 50.109.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the LRG documents are updated, the staff will wait until the ISGs have been incorporated into the LRG documents before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. The review process for revising NUREGs, like NUREG 1800 and 1801, involves public comment and review by the Committee to Review Generic Requirements. After the LRG documents have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

5.0 RESPONSIBILITIES AND AUTHORITIES

All NRC staff members who participate in the review and inspection of license renewal programs and activities are responsible for reading, understanding, and applying the guidance in this instruction.

5.1 Roles and Responsibilities for the Review of ISGs

A. GENERAL

Division of Regulatory Improvement Programs

The DRIP director is responsible for the overall development and implementation of the license renewal program and license renewal activities.

License Renewal and Environmental Impacts Program

The PD-RLEP is responsible for oversight of license renewal activities, process development activities, overall regulatory compliance, and implementation of the license renewal program.

The Chief of RLEP License Renewal Section B (RLEP-B) is responsible for the general oversight and implementation of license renewal work planning activities. The RLEP-B section chief will provide direction and assistance in the development and approval of evaluation plans to ensure effective allocation of resources, responsiveness, and quality of work. The RLEP-B section chief assigns the ISG coordinator, ISG lead PM and the project managers to work with the technical staff to develop the ISGs.

The ISG coordinator is responsible for the initial review, tracking the ISG through to resolution. The ISG Coordinator is also responsible for maintaining the list of licensees holding renewed licenses to which the approved compliance ISG applies. The ISG Coordinator will prepare, for signature by the director of DRIP, the letter requesting the licensees holding renewed license to ensure their FSARs are updated to include the compliance ISGs.

The ISG lead PM is responsible for clarifying the issue with the originator, drafting or revising the assigned proposed ISG, obtaining a TAC number, working with the cognizant staff to address the issue, resolving any comments received during the ISG review process, and processing the draft or revised ISG through the various levels of review both inside and outside of RLEP. The ISG lead PM will be the point of contact for their assigned ISG.

Technical Branches

The technical branches evaluate the technical aspects of the proposed ISG. Staff involved with the review should be familiar with the requirements of the rule; the guidance provided in the statements of consideration that accompanied the rule, the staff SRP-LR, the GALL report, and RG 1.188; and the industry guidance in NEI 95-10. The technical branches are responsible for developing the documented evaluations for compliance ISGs.

NRR Management

Division directors, program directors, and the regions will assist in resolving concerns relating to the ISG, including schedules, resources, priorities, and technical issues.

The Office of the General Counsel

Reviews the ISG from a regulatory and legal perspective.

Offices/Divisions/Branches

Other offices, divisions, and branches are responsible for reviewing and concurring consistent with the established schedule.

6.0 PERFORMANCE MEASURES

The ISG coordinator should provide an annual status update to the RLEP program director. The performance measures provide the following goals:

- Provide a response to the originator on the status and potential resolution approach within 30 days of initial contact with RLEP.
- Issue 90 percent of the proposed ISGs for comment within 180 days of initial contact with RLEP.

- Issue 90 percent of the final ISG positions within 120 days of the end of the comment period provided in the comment letters.
- Issue 100 percent of the final ISG positions within two years.

7.0 PRIMARY CONTACT

Jack Cushing, NRR/DRIP/RLEP, (301) 415-1424, JXC9@NRC.GOV

8.0 RESPONSIBLE ORGANIZATION

NRR/DRIP/RLEP

9.0 EFFECTIVE DATE

August 15, 2003

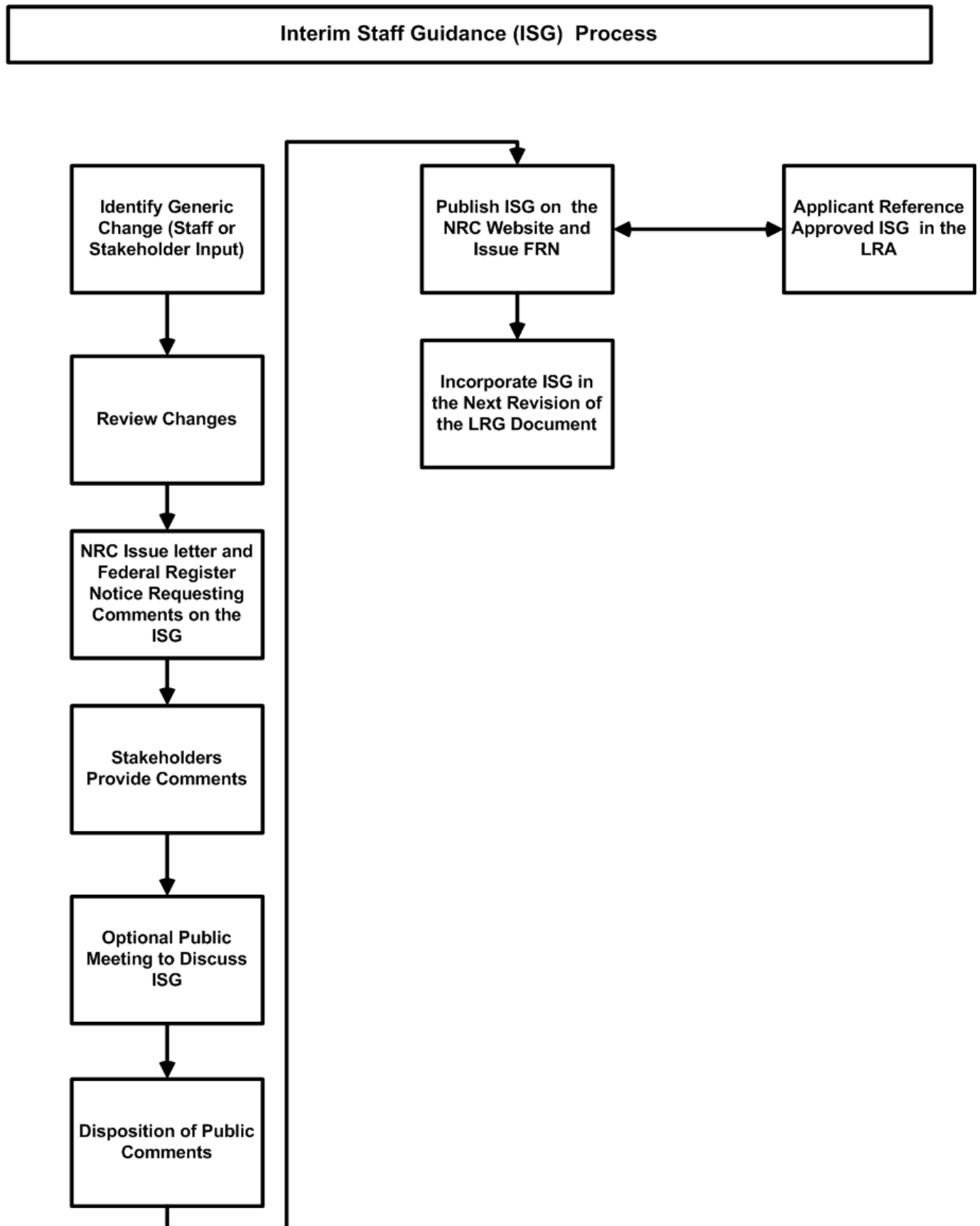
10.0 REFERENCES

1. 10 CFR Part 54, "Requirement for Renewal of Operating Licenses for Nuclear Power Plants."
2. Regulatory Guide 1.188, "Standard Format and Content for Applications to Renew Nuclear Power Plant Operating Licenses."
3. NUREG-1800, "Standard Review Plan for Review of License Renewal Applications for Nuclear Power Plants." (SRP-LR)
4. NUREG-1801, "Generic Aging Lessons Learned (GALL) Report."
5. NEI 95-10, Rev. 3, "Industry Guidelines for Implementing the Requirements of 10 CFR Part 54 - The License Renewal Rule."
6. NRR Office Letter No. 500, Rev. 2, "Procedures for Controlling the Development of New and Revised Generic Requirements for Power Reactor Licensees."

Appendix A: Change History

This is a new instruction.

Appendix B: Interim Staff Guidance Memorandum Process Flow Chart



NRC Response
to
NEI Comments on ISG Process

By letter dated October 29, 2002, NEI provided the following comments on the interim staff guidance (ISG) process.

NEI Comment:

We believe that the backfitting of license renewal evaluations falls into two distinct categories: those of the current term through the 10 CFR 50 regulations, and those of the extended period of operation. A license renewal backfit evaluation for the current term might apply to plants, whether or not a plant had applied for renewal.

Response:

The license renewal ISG process only applies to applicants for license renewal and licensees holding renewed licenses. The license renewal rule contains a provision in 10 CFR 54.37(b) for requiring licensees holding a renewed license to include in the final safety analysis report (FSAR) update any systems, structures and components (SSCs) newly identified that would have been subject to an aging management review or a time-limited aging analyses in accordance with 10 CFR 54.21. Therefore, license renewal ISGs involving matters covered by 10 CFR 54.37(b) do not involve backfits. However, ISGs that do not involve newly identified SSCs, would for licensees holding a renewed license, be subject to the requirements of 10 CFR 50.109, the backfit rule.

For licensees holding a renewed license, the license renewal regulations in 10 CFR 54.37 (b) require:

After the renewed license is issued, the FSAR update required by 10 CFR 50.71(e) must include any systems, structures, and components newly identified that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with §54.21. This FSAR update must describe how the effects of aging will be managed such that the intended function(s) in §54.4(b) will be effectively maintained during the period of extended operation.

Therefore, only for ISGs involving newly identified SSCs that would have been subject to an aging management review or evaluation of time-limited aging analyses in accordance with 10 CFR 54.21, the regulations require a licensee holding a renewed license to submit in its next FSAR update a description of how the effects of aging will be managed.

ISGs apply to the period of extended operation. Since licensees will not enter the period of extended operation until after the license renewal guidance (LRG) are updated, the staff will wait until the ISGs have been incorporated into the LRGs before informing the licensees of the requirement to include the information on the applicable ISGs in their next FSAR update. After the LRGs have been revised to include the ISGs the staff will send a letter to each licensee holding a renewed license informing them of the ISGs they need to address in their next FSAR update.

NEI Comment:

Second, we have suggested a clarification and an expansion of the Office of General Counsel's (OGC's) role in the process. We believe that OGC should determine whether the ISG is providing an improvement to the process beyond the regulations, thus, constituting a backfit, or whether the ISG represents a clarification that is necessary to comply with the regulations. In each case, OGC will provide a review and determination of the ISG's consistency with the current regulations. In the cases where backfit considerations are involved, OGC's input should clearly indicate whether the ISG was developed to establish compliance with some regulatory provisions where the industry would not necessarily otherwise be in compliance or whether the ISG represents only an improvement or clarification that is beyond the interpretation of 10 CFR 50 or 10 CFR 54 requirements (10 CFR 50.109).

Response:

The ISGs are generally identified by a technical branch in the Office of Nuclear Reactor Regulation (NRR) to address a technical issue. The technical staff with branch chief review initially determines whether the issue involves a clarification only, or whether 10 CFR Part 54 requires that the license renewal applications address the issue. Only branch chief concurrence is needed for a clarification issue. If the issue involves compliance with the regulations, then the responsible division director reviews the issue. OGC's role in these matters is discussed below.

NEI Comment:

In each case, OGC will provide a review and determination of the ISG's consistency with the current regulations. In the cases where backfit considerations are involved, OGC's input should clearly indicate whether the ISG was developed to establish compliance with some regulatory provisions where the industry would not necessarily otherwise be in compliance or whether the ISG represents only an improvement or clarification that is beyond the interpretation of 10 CFR 50 or 10 CFR 54 requirements. On these issues, OGC determinations will be made available to the public.

Response:

While OGC reviews all ISGs, OGC's advice to the staff is protected by attorney-client privilege and is not released to the public.

NEI Comment:

Finally, we believe this document provides an opportunity to significantly improve the overall stability and predictability of the rule for future applicants. The method for providing this improvement rests with establishing a more formal process for determining whether those ISGs that do not pass a backfit evaluation should even be issued. We suggest that the NRC perform a formal evaluation of the ISG impact on stability and predictability of the change vs. the benefit and establish that there is a clear benefit with proceeding with issuing these ISGs.

Response:

One of the staff's goals in developing the ISG process was to reduce unnecessary regulatory burden by increasing the stability and predictability of the license renewal process. The other goal was to improve the effectiveness and efficiency of the process of updating the license renewal guidance documents. The staff does issue a documented evaluation with each ISG. The documented evaluation provides a description of the issue in sufficient detail, such that an informed reader can understand the issue, its basis, significance, applicability (e.g., generic, BWRs only), and ramifications. The staff will document its analysis of the proposed ISG in terms of regulatory requirements, established staff positions, industry standards, or other relevant criteria.